example, U.S.Patent 4,839,341 (including claims 3 and 5) cited and supplied with the previously filed Information Disclosure Statement.

The word "fortified" is used in claim 25 for its common meaning, "to make strong" in the sense of better maintaining the potency of the lyophilized insulin powder.

Claims 1-3, 13 and 14 stand rejected under 35 U.S.C. §102(a) as being anticipated by Havelund et al PCT publication WO 95/07931 and claims 1-26 were rejected under 35 U.S.C. §103 as being unpatenable over Havelund et al PCT publication WO 95/07931 in view of Hashimoto [*Pharm. Res.* **6**, 171-176 (1989)] and Howey et al., [*Diabetes* **43**, 396-402 (1994)]. These rejections are respectfully traversed.

Without conceeding that the cited references anticipate or render obvious the pending claims, applicants submit the Declaration of inventor Beckage under Rule 131 to traverse the rejections. The effective date of the princpal Havelund et al citation, supporting both the §102(a) and §103 rejections, is less than a year prior to the filing date of the subject application (March 23, 1995 versus June 7, 1995). Thus, the reference can be traversed under 37 C.F.R. §1.131 by a showing of a prior reduction to practice.

In particular, the Beckage Declaration presents facts, supported by photocopies of original notebook records (Exhibits 1, 2 and 3), that demonstrate a reduction to practice of the subject invention prior to the effective date of the cited Havelund et al PCT publication WO 95/07931, used as the principal document for rejecting the pending claims.

As attested to in the declaration, and as recorded in the original signed and witness notebook records of inventor Beckage, an aqueous solution of a fatty acid-acylated insulin (C16 insulin - namely N^{ϵ}-Lys^{B29}-palmitoyl-human fatty acid -acylated insulin(Exhibit 1)), containing 0.35 mole of zinc per mole of insulin (Exhibit 2), having 2.5 mg/ml of *m*-cresol (Exhibit 1) and

a pH of approximately 7.5 (Exhibit 3), was prepared prior to 23 March 1995, the effective §102(a) date of the cited Havelund et al PCT publication WO 95/07931. This composition meets each of the essential limits of claim 1 and thus constitutes a reduction to practice of the invention defined by that claim as of a date earlier than 23 March 1995.

In light of the foregoing remarks, Applicants respectfully submit that claims 1-26 are patentable, and urge allowance of these claims and passage to issue of the present application.

Respectfully submitted,

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